

AMENDMENTS

Amendments to the Specification:

Please replace paragraphs [0001] – [0003] with the following amended paragraphs:

[0001] This application claims the benefit of ~~priority under 35 U.S.C. §119(e) from co-pending, commonly owned U.S. provisional patent application serial number U.S. Provisional Application No. 60/477,573, entitled “Apparatus and Method For Radiosurgery,” filed June 11, 2003, and U.S. Provisional Application No. . This application also claims the benefit of priority under 35 U.S.C. §119(e) from co-pending, commonly owned U.S. provisional patent application serial number 60,477,551, entitled “Apparatus and Method for Cardiac Treatment,” filed June 11, 2003.~~

[0002] The present invention relates to ~~treatment~~ creation of lesions whose positions are significant during the course of treatment, such as lesions located on the heart, or on organs close to the heart. More particularly, the invention relates to a method and system for treating cardiac-related diseases, and for ~~treating~~ creating lesions on anatomical regions that undergo motion, such as motion due to pulsating arteries.

[0003] A number of medical conditions involve creating lesions whose positions are significant during the course of treatment, such as lesions that are located on the heart or on other organs close to the heart. In many cases, it is necessary to ~~treat~~ create lesions on anatomical regions that undergo rapid motion, for example motion due to pulsating arteries. Traditionally, the ~~treatment~~ creation of such lesions or moving anatomical regions has required invasive surgery, such as open heart surgery for cardiac-related treatments.

Please replace paragraph [0005] with the following amended paragraph:

[0005] In general, possible complications of an invasive surgery are significant, and include stroke, bleeding, infection, and death. One technique for avoiding the complications of invasive surgery is radiosurgery, which is recognized as being an

effective tool for noninvasive surgery. Radiosurgery involves directing ~~precisely focused~~ radiosurgical beams onto target regions, in order to create lesions to necrotize tumorous tissue. The goal is to apply a lethal or other desired amount of radiation to one or more tumors, or to other desired anatomical regions, without damaging the surrounding healthy tissue. Radiosurgery therefore calls for an ability to accurately ~~focus-direct~~ the beams upon a desired target ~~(e.g. a tumor)~~, so as to deliver high doses of radiation in such a way as to cause only the ~~tumor or other~~ target to receive the desired dose, while avoiding critical structures. The advantages of radiosurgery over open surgery include significantly lower cost, less pain, fewer complications, no infection risk, no general anesthesia, and shorter hospital stays, most radiosurgical treatments being outpatient procedures.

Please replace paragraph [0008] with the following amended paragraph:

[0008] The present invention is directed to the radiosurgical ~~treatment of lesions~~ creation of lesions whose positions are significant during the course of treatment, and to the radiosurgical treatment of anatomical regions that undergo motion. For example, these lesions and/or anatomical regions may be located on beating heart walls, or on organs near the heart, or on pulsating arteries.

Please replace paragraph [0015] with the following amended paragraph:

[0015] In one form of the invention, using techniques similar to those disclosed in U.S. Pat. No. 6,501,981 (the "'981 patent")(owned by the assignee of the present application and hereby incorporated by reference in its entirety), the motion of tissue at or near the target is determined. For example, a look-up table of positional data may be established for a succession of points along the each of the respiratory cycle and the heartbeat cycle. Motion points for the respiratory cycle include position information obtained in response to both respiration and heartbeat of the patient. Positional information for the heartbeat cycle can be obtained through imaging of the tissue while the patient is holding his breath. A table ("table 2") containing this positional information

can provide the basis for first signal-F2. The second signal-Signal-F1, on the other hand, can be obtained by subtracting data from the table for the heartbeat cycle (obtained by having the patient hold his breath) from the data from the composite motion (formed of both respiration and heartbeat), since the resulting table ("table 1") corresponds to motion caused substantially only by respiration. Positional changes for the x-ray source can be applied based on superposition of data from table 1 and table 2.

Please replace paragraphs [0021] – [0024] with the following amended paragraphs:

[0021] In the present invention, the techniques of radiosurgery are used to treat target tissue by creating radiosurgical lesions. These lesions are created in anatomical target regions located in places that undergo constant motion, such as the heart walls of a beating heart. The motion of the target, due to respiration and heart beat, is continuously tracked during treatment, so that the radiosurgical beams remain properly ~~focused and~~ directed onto the desired target regions in the patient's anatomy.

[0022] FIG. 1 illustrates a radiosurgical treatment system, known in the art. The radiosurgery system 100 shown in FIG.1 may, for example, represent the ~~CyberKnife~~ CyberKnife® system ("CyberKnife") developed by Accuray, Inc. In overview, the conventional radiosurgery system 100 includes a radiosurgical beaming apparatus 102; a positioning system 104; imaging means 106; and a controller 108. The system 100 may also include an operator control console and display 140. The radiosurgical beaming apparatus 102 generates, when activated, a collimated radiosurgical beam (consisting of x-rays, for example). The cumulative effect of the radiosurgical beam, when directed to ~~and focused onto~~ the target, is to necrotize or to create a lesion in a target 118 within the patient's anatomy. By way of example, the positioning system 104 is an industrial robot, which moves in response to command signals from the controller 108. The beaming apparatus 102 may be a small x-ray linac mounted to an arm 112 of the industrial robot 104. The imaging means 106 may be an x-ray imaging system, having a pair of x-ray sources 124 and 125 for generating diagnostic imaging beams 126 and 127, and x-ray image detectors 136 and 137.

[0023] In the prior art system 100, the imaging means 106 generates real-time radiographic images of the anatomical region containing the target, by transmitting one or more imaging beams through the target. The controller 108 determines the real-time location of the target, by comparing the real-time radiographic image with pre-operative CT (or MRI) scans of the target that have been stored within the computer. The positioning system 104 manipulates the position of the radiosurgical beam, in response to control commands from the controller 108, so as to keep the radiosurgical beam properly ~~focused onto~~ directed to the target.

[0024] In order to account for the motion of a moving target, for example due to respiration of the patient, patients have typically been advised to hold their breath while being scanned by the CT scanner, prior to treatment. In this way, the moving patient is fixed, and therefore the scan does not have any motion artifacts. More recently, new radiosurgical devices, such as ~~the CyberKnife~~ CyberKnife® system, have been employing new technologies for treating moving targets. For example, Accuray recently revealed a new product, Synchrony®, which is Accuray's new system for delivering dynamic radiosurgery to tumors that move with respiration. The Synchrony® system is described in U.S. Pat. No. 6,501,981 (the "'981 patent"), entitled "Apparatus And Method For Compensating For Respiratory And Patient Motions During Treatment," which issued on December 31, 2002 to A. Schweikard and John R. Adler. The '981 patent is owned by the assignee of the present application, and is hereby incorporated by reference in its entirety. The Synchrony® system precisely tracks tumors in or near the lungs as they move, enabling highly ~~focused~~ directed beams of radiation to destroy the tumors with minimal damage to adjacent normal tissue. In particular, the Synchrony® system records the breathing movements of a patient's chest, and combines that information with sequential x-ray pictures of tiny markers inserted inside or near the tumor. In this way, the Synchrony® system enables precise delivery of radiation during any point in the respiratory cycle.

Please replace paragraph [0028] with the following amended paragraph:

[0028] The system 200 includes a radiosurgical beam source 202 for generating one or more radiosurgical beams, preferably x-rays. The cumulative effect of applying the radiosurgical x-ray beams during the treatment period is to create at least one lesion in the target, so that the desired clinical purpose can be accomplished. In the illustrated embodiment, as in the prior art, the radiosurgical beam source 202 is a small x-ray linac. The system 200 also includes a surgical beam positioning system 204. As in the prior art, the positioning system 204 in the illustrated embodiment is an industrial robot, which moves in response to command signals from a central controller 208. The x-ray linac 202 is mounted to an arm of the industrial robot 204. It should be noted that other types of beam source 202 and positioning system 204 known in the art may be used, without departing from the scope of the present invention.

The central controller 208 is preferably a multi-processor computer. The controller 208 may also include a storage unit 218 (for example, for storing the pre-operative CT scan data), and an operator console and display 240. The controller 208 preferably has a plurality of processing or controller units, including, inter alia: 1) treatment ~~planning~~ software 210 for generating, based on the CT scan data generated by the CT scanner 212, a treatment plan that defines a plurality of x-ray beams appropriate for creating one or more lesions in an anatomical target region in the heart; and 2) a controller unit 300 for sending command signals to the positioning system 204 (i.e. the robot), so as to adjust the relative position of the beam source 202 and the target. The treatment plan contains information regarding the number, intensities, positions, and directions of the x-ray beams that are effective to create at least one radiosurgical lesion.

Please replace paragraphs [0038] – [0039] with the following amended paragraphs:

[0038] In one embodiment of the invention, a look-up table of positional data may be established for a succession of points along each of the respiratory cycle and the heartbeat cycle, using techniques similar to those disclosed in the '981 patent. Motion points for the moving target include position information obtained in response to both respiration

and heartbeat of the patient. Positional information for the heartbeat cycle can be obtained through imaging of the tissue while the patient is holding his breath. A table ("table 2") containing this positional information can provide the basis for the second signal F2. The second signal ~~Signal F1~~, on the other hand, can be obtained by subtracting data from the table for the heartbeat cycle (which was obtained by having the patient hold his breath) from the data from the composite motion (formed from both respiration and heartbeat), since the resulting table ("table 1") corresponds to motion caused substantially only by respiration. Positional changes for the x-ray source can be applied based on superposition of data from table 1 and table 2.

[0039] As explained earlier, the first correction factor accounts for the breathing motion, and the second correction factor accounts for the cardiac pumping motion. As mentioned earlier, the first and second correction factors are superposed, to generate a ~~combine~~ combined correction factor that can be applied to the controller subunit 300, so that the composite motion due to both respiration and heart beat can be accounted for.

Please replace paragraphs [0041] – [0042] with the following amended paragraphs:

[0041] In one embodiment, the step of generating the requisite corrections (for adjusting the relative position of the x-ray source and the target, in near real time) to the command signals from the subunit 300 may include: 1) extrapolating the detected motion of the target into a complete cycle; and 2) synchronizing the command signals with the extrapolated motion of the target region, so as to modify the relative positions of the beam source and the target based on the extrapolated motion information. The changes in position of the target is constantly tracked over time, throughout the treatment period. The resulting modifications in the relative positions of the beam source 202 and the target are communicated to the beam source 202 and the positioning system 204 by the controller 208. As a result, the position, direction, and intensity of the radiosurgical beams are continuously adjusted, so that an accurate radiation dose can be applied to the appropriate regions of the patient's anatomy in accordance with the treatment plan,

throughout the radiosurgical treatment. The plurality of radiosurgical beams remain ~~focused onto~~ directed to the target, in accordance with the treatment plan, throughout the duration of the treatment, and the radiosurgical x-ray beam source tracks the movement of the target.

[0042] As an improvement, instead of tracking the changes constantly over time, the system 200 can, for one component (for example, the lower frequency component F1 derived from the breathing motion), have a relatively static correction appropriate for just the “peak” of the respiratory cycle, in another embodiment of the present invention. In this embodiment, treatment by creating radiosurgical lesions may be performed only at the peaks of the respiratory cycle using the command signals modified by only the static correction factor (from breathing), and a dynamic (constantly monitored and changing) high-frequency correction factor, derived from heartbeat.

Please replace the abstract with the following amended abstract:

A method and system is presented for treating moving target regions in a patient's anatomy by creating radiosurgical lesions. The method includes ~~Based on the CT scan data, a treatment plan is generated that defines the requisite beam intensities and paths. The position of the target region is determined in near real time. The composite motion of the target region, due to respiration and heartbeat, is tracked. Signals representative of the change (caused by the composite motion) in the position of the target region at a current time, compared to the position of the target region in the CT scan, are generated. In response, the relative position of the x-ray source and the target is adjusted, so as to account for the composite motion of the target. This process is repeated throughout the treatment. As a result, the x-rays are continually focused onto the target region in accordance with the treatment plan, while the x-ray source tracks the motion of the target region, determining a pulsating motion of a patient separately from a determining of a respiratory motion, and directing a radiosurgical beam, from a radiosurgical beam source, to a target in the patient based on the determining of the pulsating motion. Directing the radiosurgical beam to the target may include creating a lesion in the heart to inhibit atrial fibrillation. The method may further include determining the respiratory motion of the~~

patient, and compensating for movement of the target, due to the respiratory motion and the pulsating motion of the patient, in the directing of the radiosurgical beam based on the determining of the respiratory motion and the determining of the pulsating motion.